IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

CONSTANCE SUNDELL, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	Case No. 8:21-cv-00032

DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM IN SUPPORT OF ITS MOTION TO CERTIFY ORDER UNDER 28 U.S.C. § 1292(b) FOR INTERLOCUTORY APPEAL AND FOR STAY OF PROCEEDINGS

Defendant Novartis Pharmaceuticals Corporation ("NPC") respectfully requests that the Court certify its September 8, 2021 Memorandum and Order, Filing No. 51 ("Order"), for an immediate appeal pursuant to 28 U.S.C. § 1292(b), and for a stay of proceedings.

INTRODUCTION AND BACKGROUND

A district court is permitted to certify for interlocutory appeal under 28 U.S.C. § 1292(b) an order that "involves a controlling question of law as to which there is substantial ground for difference of opinion," when "an immediate appeal from the order may materially advance the ultimate termination of the litigation." This Court's Order meets these criteria as it involves fundamental, threshold questions of law to which there is substantial ground for difference of opinion and that will drastically impact litigation of this matter.

In its Memorandum in Support of its Motion to Dismiss, NPC argued that plaintiff's claims were preempted for two reasons. First, NPC argued that plaintiff's claims are preempted under

Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 352-53 (2001).[1] NPC relied on case law for the widely-accepted proposition that *Buckman* is not limited to medical device cases and, instead, applies to pharmaceutical cases like this one.[2]

In its Order, the Court denied NPC's motion and held that plaintiff's claims are not preempted under *Buckman* solely because that case is "inapplicable" as *Buckman* concerned a medical device governed by the "Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act [("FDCA")], which included an express preemption provision for medical devices."[3] The Court's opinion is in conflict with persuasive precedent and is unsupported by any applicable authority.

Second, NPC argued that plaintiff's claims are preempted because plaintiff failed to allege "newly acquired information" that would trigger the Changes Being Effected ("CBE") regulations.[4] NPC relied on precedent from two Circuit Courts of Appeals (as well as various district court opinions) that establish that, in determining whether a plaintiff can avoid preemption at the motion to dismiss stage, a court must scrutinize the complaint (and the relied-upon information) to ensure that it includes allegations of new information that demonstrably meets the regulatory definition for "newly acquired information."[5] NPC also cited recent binding Supreme Court precedent holding that preemption questions are to be decided by the judge, not a jury.[6] The

[1] Filing No. 34 at 9-11.

[2] Filing No. 34 at 9-11 (citing case law).

[3] Filing No. 51 at 6, 8.

[4] Filing No. 34 at 13-20.

[5] *Id.*

[6] Filing No. 40 at 1 n.2 (citing *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679-80 (2019)).

Order failed to acknowledge or cite this precedent, let alone attempt to distinguish its applicability to this case.

Instead, the Court denied NPC's motion holding that "[w]hether the defendants responsibility to amend its label was triggered based on physician-reported adverse events, and the defendants own re-evaluation of its Phase III clinical trial data . . . is a question of fact for a jury to resolve, and a question that undoubtedly will require testimony and evidence from qualified experts."[7] But in *Albrecht*, the Supreme Court held that "courts should treat the critical [preemption] question not as a matter of fact for a jury but as a matter of law for the judge to decide."[8] The *Albrecht* Court further held that the "complexity of the preceding discussion of the law helps to illustrate why we answer this question by concluding that the [preemption] question is a legal one for the judge, not a jury," and in such instances, "courts may have to resolve subsidiary factual disputes that are part and parcel of the broader legal question."[9] And according to the Supreme Court, "treat[ing] the preemption question as one of fact, and not law" is reversible error and will result in such an order being vacated and remanded based on the precedent set by

[7] Filing No. 51 at 11. The Court's finding that the information "published online prior to the plaintiffs' Beovu injections . . . concluded that there was a causal connection between Beovu injections and retinal vasculitis" is not supported by plaintiffs' allegations or the record. Filing No. 51 at 10 (citing Filing No. 34 at 19 and Filing No. 30 at 17-18). Plaintiff **does not allege** that the purported "causal connection" pre-dates plaintiff's exposures. *See* Filing No. 30 ¶ 66. Nor could she. The quoted language in plaintiff's amended complaint, which is relied on by the Court, **did not appear** in the January 17, 2020 publication. Rather, the quoted language appears in an article that was published in July 2020, months after plaintiff was last injected with Beovu®, and is therefore irrelevant to the threshold question of whether plaintiff has adequately pled *pre-exposure* "new evidence" that could have triggered a right to unilaterally change the FDA-approved warnings under the CBE regulations.

[8] *Albrecht*, 139 S. Ct. at 1679.

[9] *Id.* at 1679-80 (quotations and cites removed).

Albrecht.[10] The Court's holdings are both contrary to law and, if not certified, would create a split of decisions within—and outside of—this Circuit.[11]

The effect of the Order on these proceedings illustrates the need for an appeal to materially advance the ultimate termination of these cases. Absent an interlocutory appeal, complicated and expensive discovery, pretrial proceedings, and potentially unnecessary and complicated trials will ensue, which would be rendered a nullity if the Eighth Circuit were to reverse the Order. An immediate appeal would eliminate this risk and afford the Eighth Circuit an opportunity to provide clarity to admittedly difficult legal issues that the Court must decide.

For these reasons and those set forth below, the Order meets all of the factors of 28 U.S.C. § 1292(b), and the Court should grant this Motion and amend the Order to certify it for interlocutory appeal. In the interests of justice and to render an immediate appeal most effective, the Court should also stay these proceedings pending resolution of the petition for appeal and any resulting interlocutory appeal.

ARGUMENT

Section 1292(b) provides for the permissive appeal of an otherwise unappealable order if three criteria are met: (1) the order involves a controlling question of law; (2) there is substantial ground for a difference of opinion; and (3) certification may materially advance the ultimate

[10] *Id.* at 1680-81.

[11] *See, e.g., Ridings v. Maurice*, 444 F. Supp. 3d 973, 990-91 (W.D. Mo. 2020) (quoting *Albrecht*, 139 S. Ct. at 1679) (holding *Albrecht* preemption hearing and finding claims preempted by the FDCA); *see also Duncan v. Allergan, Inc.*, No. CV 18-8047 FMO (Ex), 2020 WL 6204563, at *6 (C.D. Cal. Sept. 4, 2020) (stating that preemption is for the judge, not the jury).

termination of the litigation.[12] Courts often "begin[] with the first and third criteria, which present related inquiries."[13]

While review is discretionary, "[i]nterlocutory appeal is favored where reversal would substantially alter the course of the district court proceedings or relieve the parties of significant burdens."[14] The "idea" behind § 1292(b) "was that if a case turned on a pure question of law, something the court of appeal could decide quickly and cleanly without having to study the record, the court should be enabled to do so without having to wait [until] the end of the case."[15] District courts routinely take into account practical considerations when deciding whether to certify an order for appeal under Section 1292(b).[16] As discussed below, the September 8 Order satisfies the criteria for interlocutory appeal.

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[12] 28 U.S.C. § 1292(b); *Union Cnty., Iowa v. Piper Jaffray & Co., Inc.,* 525 F.3d 643, 646 (8th Cir. 2008); *White v. Nix*, 43 F.3d 374, 377 (8th Cir. 1994).

[13] *Bussing v. Cor Clearing, LLC*, No. 8:12-CV-238, 2014 WL 3548278, at *1 (D. Neb. July 17, 2014) (Gerrard, J.) (citations omitted) (stating that "there is substantial overlap between the first and third criteria: 'a question is controlling, even though its decision might not lead to reversal on appeal, if interlocutory reversal might save time for the district court, and time and expense for the litigants.'").

[14] *Gaylord Ent. Co. v. Gilmore Ent. Grp.*, 187 F. Supp. 2d 926, 957 (M.D. Tenn. 2001); *see also Katz v. Carte Blanche Corp.*, 496 F.2d 747, 756 (3d Cir. 1974) (when deciding whether to authorize an interlocutory appeal, courts should be concerned with avoiding harm to a party from a possibly erroneous interlocutory order and avoiding possibly wasted litigation expense and time).

[15] *See Delock v. Securitas Sec. Servs. USA, Inc.*, 883 F. Supp. 2d 784, 791 (E.D. Ark. 2012) (granting appeal under 1292(b) because the enforceability of a class action waiver in a contract's arbitration clause was a pure question of law) (citation omitted)).

[16] *See* 16 C. Wright, A. Miller & G. Cooper, *Federal Practice and Procedure* § 3930 (3d ed. 2004) (Section 1292(b) "inject[s] an element of flexibility" into the rules regarding appellate jurisdiction and its "three factors should be viewed together as . . . a direction to consider the probable gains and losses of immediate appeal."); *AT&T Commc'ns of the Midwest, Inc. v. Qwest Corp.*, Civil No. 06-3786, 2007 WL 1994047, at *1 (D. Minn. July 3, 2007) (determining whether an order involves a "'controlling question of law' can encompass practical or legal issues").

I. THE SEPTEMBER 8, 2021 ORDER SATISFIES THE STANDARD FOR INTERLOCUTORY APPEAL UNDER 28 U.S.C. § 1292(b) AND SHOULD BE CERTIFIED FOR APPEAL.

A. The Order Rests On Controlling Questions of Law And Reversal Would Materially Advance the Ultimate Resolution of This Litigation.

The Motion to Dismiss and the Court's resulting Order addressed three pure questions of law. The applicability of *Buckman* implied preemption outside the medical device context is plainly a question of law that has been decided as such—and contrary to the Court's Order—on numerous occasions.[17] Likewise, whether a plaintiff meets its burden to allege newly acquired information in order to avoid preemption is a question of law that has been decided *as a matter of law* by multiple courts of appeals at the motion to dismiss stage.[18] Finally, the determination of

[17] *See, e.g.*, *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 944 (8th Cir. 2011) ("The Court in *Buckman* specifically applied field preemption to state-law fraud-on-the-FDA claims because policing fraud against federal agencies 'is hardly a field which the States have traditionally occupied.'") (citing *Buckman*, 531 U.S. at 347); *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012) (holding plaintiff's claim against drug manufacturer—like plaintiff's claims here—preempted under *Buckman* because it required plaintiff to prove fraud-on-the FDA to recover for failure to warn); *In re Trasylol Prods. Liab. Litig.-MDL-1928*, 763 F. Supp. 2d 1312, 1325 (S.D. Fla. 2010) ("*Buckman* is also implicated where a plaintiff seeks to use a violation of an FDA reporting requirement as proof of negligence."); *Bader Farms, Inc. v. Monsanto Co.*, Case No. 1:16-CV-299 SNLJ, 2017 WL 633815, at *3 (E.D. Mo. Feb. 16, 2017) (whether federal regulatory bodies fulfilled their duties with respect to the entities they regulate is "'inherently federal in character'") (citing *Buckman*, 531 U.S. at 347). *Metz v. Wyeth, LLC*, 872 F. Supp. 2d 1335, 1342 n.7 (M.D. Fla. 2012), *aff'd*, 525 F. App'x 893 (11th Cir. 2013) ("To the extent Plaintiffs contend that Actavis failed to supply relevant information to the FDA, Plaintiffs' claim may be viewed as relying on a fraud-on-the-FDA theory of liability. It is undisputed that 'fraud on the FDA claims' are impliedly preempted by the FDCA.")

[18] *See In re Celexa and Lexapro Mktg. and Sales Prac. Litig.*, 779 F.3d 34 at 42-43 (1st Cir. 2015) (analyzing the content of academic studies referenced in plaintiff's complaint at the motion to dismiss stage to determine if the FDA was aware of the information prior to approval); *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d. Cir. 2019) (analyzing at the motion to dismiss stage that plaintiff's references to reports and studies addressing problematic bleeding events after users took Eliquis did not reveal risks of a different type or greater severity or frequency); *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 672-63 (S.D.N.Y. 2017), *aff'd*, 919 F.3d 699 (2d Cir. 2019) (analyzing the content of various medical reports, journal studies, published articles, and news articles to determine that plaintiff has not adequately plead the existence of newly

what questions are committed to the Court, rather than left for the jury to decide, is purely a question of law as required by *Albrecht*.[19] These preemption inquiries present pure questions of law appropriate for interlocutory review.

These are controlling questions of law because their "resolution is quite likely to affect the further course of the litigation, even if not certain to do so."[20] A question of law is also controlling, "even though its decision might not lead to reversal on appeal, if interlocutory reversal might save time for the district court, and time and expense for the litigants.'"[21]

Here, the applicable preemption legal questions affect the further course of the litigation and there will be practical and legal consequences if the Eighth Circuit reverses the Court's holdings. For example, an appellate decision confirming that *Buckman* applies in this context means that plaintiff's claims fail—allegations that NPC misrepresented the safety of Beovu® or concealed safety information from its submissions to FDA would be preempted.

Additionally, the Eighth Circuit could confirm that a plaintiff cannot merely allege that new information *exists* without alleging and establishing that such information meets the regulatory definition of newly acquired information (e.g., whether the information demonstrates "reasonable evidence of a causal association with a drug" and whether the alleged new information "reveal[s] risks of a different type or greater severity or frequency than previously included in

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acquired information because it "is well-established that preemption may be analyzed and decided at the motion to dismiss stage").

[19] *Albrecht*, 139 S. Ct. at 1679-80.

[20] *Bussing*, 2014 WL 3548278, at *1 (citing *Sokaogon Gaming Enter. Corp. v. Tushie–Montgomery Associates, Inc.,* 86 F.3d 656, 659 (7th Cir. 1996)); *id.* ("controlling" means "serious to the conduct of the litigation, either practically or legally.").

[21] *Id.* (quoting *Johnson v. Burken,* 930 F.2d 1202, 1206 (7th Cir. 1991) (quoting Wright *et al., supra*, § 3930).

submissions to FDA").[22] Such a ruling would prove fatal to plaintiff's complaint as there are **no allegations** that the adverse reports[23] referenced in the complaints satisfy these requirements.

Finally, in the likely event that the Eighth Circuit applies binding Supreme Court precedent and confirms that preemption questions are committed to the Court, and cannot be left for the jury, then an evidentiary hearing would potentially be required before the Court denies NPC's motion.[24] This Court's inquiry necessarily would need to address whether the facts pled are sufficient to trigger the CBE regulation and, only if properly pled, whether those facts then actually exist based on a consideration of evidence.

The implications for an appellate ruling in this case demonstrate that this is a controlling question of law. For the same reasons, resolution of this issue may materially advance this litigation. It will clarify the scope and necessity of inquiring into the related legal questions identified above and will put all parties on firmer footing when it comes to conducting discovery, preparing for trial, and forming their overall litigation strategy.

B. There Are Substantial Grounds For Differences Of Opinion Regarding The Court's Findings.

To determine if a substantial ground for difference of opinion exists under § 1292(b), courts must examine to what extent the controlling law is unclear.[25] "The law may be unclear where the circuits are in dispute on the question and the court of appeals of the circuit has not spoken on the

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[22] 21 C.F.R. § 601.12(f)(6).

[23] As discussed above in footnote 7, the only information alleged by plaintiffs that pre-dates plaintiffs' exposures are the adverse event reports. This is because the purported causal connection relied on by the Court is not alleged to have occurred prior to plaintiff's exposures and, in fact, did not appear in the referenced publication until July 2020—long after plaintiff's exposures. *See* Supra p. 2, n. 7.

[24] *Albrecht*, 139 S. Ct. at 1679-80.

[25] *Bussing*, 2014 WL 3548278, at *1 (citing *Couch v. Telescope Inc.,* 611 F.3d 629, 633 (9th Cir. 2010)).

point."[26] Courts have found that a substantial ground for difference of opinion exists where there is "some inconsistency" in decisions.[27] The subject matter of the Court's Order satisfies this standard as it prompted conflicting rulings from federal courts across the country.

In its Order, the Court found that *Buckman* is "inapplicable" because it concerned a medical device governed by the Medical Device Amendments of the FDCA, which includes an express preemption provision for medical devices.[28] But other courts have concluded otherwise—i.e., that *Buckman* applies in the prescription drug context and that such claims are *impliedly* preempted.[29] NPC is aware of no court that has held that *Buckman* is "inapplicable" in the prescription drug

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[26] *Id.*

[27] *See Perry v. Johnston*, No. 4:09-CV-105 (CEJ), 2010 WL 546774, at *2 (E.D. Mo. Feb. 9, 2020) (finding substantial ground for difference of opinion where there was "some inconsistency" with how the issue was treated in certain districts within the Eighth Circuit); *see also Schwendimann v. Arkwright Advanced Coating, Inc.*, Civil No. 11-820-ADM/JSM,, 2012 WL 5389674, at *3 (D. Minn. Nov. 2, 2021) (substantial grounds for difference of opinion exists if there are a "sufficient number of conflicting and contradictory opinions" on the issue); *Pro-Edge L.P. v. Gue*, No. C05-4068-MWB, 2006 WL 8456918, at *2 (N.D. Iowa May 15, 2006) (finding substantial ground for difference of opinion where, *inter alia*, "courts have come to differing conclusions" with respect to the issue for appeal).

[28] Filing No. 51 at 8.

[29] *Lofton*, 672 F.3d 372 (holding plaintiff's claim against drug manufacturer preempted under *Buckman* because it required plaintiff to prove fraud-on-the FDA to recover for failure to warn); *In re Trasylol*, 763 F. Supp. 2d at 1325 ("*Buckman* is also implicated where a plaintiff seeks to use a violation of an FDA reporting requirement as proof of negligence."). In addition to being preposterous on its face, plaintiff's argument that *Buckman* is inapplicable to non-medical device cases is belied by the fact that multiple courts have applied *Buckman* to preempt "fraud-on-the-agency" claims involving products subject to regulatory statues other than the FDCA and overseen by federal agencies other than the FDA. *See, Bader Farms, Inc.*, 2017 WL 633815, at *3 (applying *Buckman* to EPA oversight); *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002) (applying *Buckman* preemption to claim relying on misrepresentations to the EPA); *Transmission Agency of N. California v. Sierra Pac. Power Co.*, 295 F.3d 918, 932 n.10 (9th Cir. 2002) (if plaintiff's "fraud claim were predicated on alleged misrepresentations before [the Federal Energy Regulatory Commission], it would still be preempted" under *Buckman* as an alleged misrepresentation under state tort law); *Lefaivre*, 636 F.3d at 944 ("*Lefaivre*") (recognizing *Buckman* field preemption applies to fraud-based claims because policing fraud against federal agencies "is hardly a field which the States have traditionally occupied") (citing *Buckman*, 531 U.S. at 347).

context, and neither plaintiff nor the Court has cited any. Thus, there is a substantial ground for disagreement on this issue based on the conflict between the Court's decision and the numerous contrary decisions.

There is also a substantial ground for difference of opinion regarding the Court's inability "to conclude that, as a matter of law, [plaintiff's information] constitute[s] newly acquired information of events or analyses revealing risks different in type or of greater severity than previously reported to the FDA."[30] This Court has held that this criteria is satisfied where an issue has not been addressed by the Eighth Circuit and it "has prompted conflicting rulings from federal courts across the country."[31]

Here, the Court denied NPC's motion holding that it is unable to decide as a matter of law that the alleged adverse event reports do not constitute newly acquired information. In doing so, the Court accepted plaintiff's conclusory allegations without analyzing whether the alleged adverse event reports meet the regulatory definition of newly acquired information.[32] This Court made a similar ruling in *Ideus v. Teva Pharms. USA, Inc.*, No. 4:106-CV-3086, 2018 WL 7958927 (D. Neb. Feb. 23, 2018) and accepted plaintiff's allegation that the reports made it "possible" for the defendants to modify the labeling without analyzing whether those reports meet the regulatory definition of newly acquired information.[33]

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[30] Filing No. 51 at 10.

[31] *Bussing*, 2014 WL 3548278, at *1 (granting motion to certify and finding a "substantial ground for difference of opinion" where a legal issue "has prompted conflicting rulings from federal courts across the country.").

[32] Filing No. 51 at 10-11.

[33] *Teva*, *2018* WL 7958927, at *1 (denying motion to dismiss without analyzing whether adverse event reports meet the regulatory definition of newly acquired information and simply accepted plaintiff's allegation that the reports made it "possible" for the defendants to modify the labeling).

In contrast, courts across the country take the conflicting (and correct) approach of scrutinizing alleged newly acquired information to ensure, *even at the motion to dismiss stage*, that it meets the regulatory definition of newly acquired information (e.g., whether the information demonstrates "reasonable evidence of a causal association with a drug" and whether the alleged new information "reveal[s] risks of a different type or greater severity or frequency than previously included in submissions to FDA").[34] This approach has been endorsed by the First Circuit,[35] Second Circuit,[36] and numerous district courts,[37] including district courts within the Eighth

[34] 21 C.F.R. § 601.12(f)(6).

[35] *See In re Celexa*, 779 F.3d 34 at 42-43 (analyzing the content of academic studies referenced in plaintiff's complaint at the motion to dismiss stage to determine if the FDA was aware of the information prior to approval).

[36] *Gibbons*, 919 F.3d at 708 (analyzing at the motion to dismiss stage plaintiff's references to reports and studies addressing problematic bleeding events after users took Eliquis and concluding that they did not reveal risks of a different type or greater severity or frequency); *Utts*, 251 F. Supp. 3d at 672-63, *aff'd*, 919 F.3d 699 (analyzing the content of various medical reports, journal studies, published articles, and news articles to determine that plaintiff has not adequately plead the existence of newly acquired information because it "is well-established that preemption may be analyzed and decided at the motion to dismiss stage").

[37] *McGrath v. Bayer Healthcare Pharm., Inc.*, 393 F. Supp. 3d 161, 168-70 (E.D.N.Y. 2019) (analyzing several reports and studies referenced in plaintiff's complaint to determine there was insufficient evidence of a causal association between the drug and the injury to support a finding of newly acquired information at the motion to dismiss stage); *Rayes v. Novartis Pharms. Corp.*, No. 5:21-cv-00201-JGB-KK, 2021 WL 2410677, at *5 (C.D. Cal. June 11, 2021) (analyzing at the motion to dismiss stage plaintiff's nearly identical allegations to determine whether plaintiffs alleged new information satisfies the regulatory definition); *Gayle v. Pfizer Inc.*, No. 19cv3451, 2020 WL 1685313, at *5 (S.D.N.Y. April 7, 2020) (finding under the motion to dismiss standard that 6,000 adverse event reports showing type 2 diabetes in patients that took cholesterol did not amount to a causal association and thus, was not newly acquired information); *id.* (concluding that unanalyzed adverse event reports "miss[] the mark," where plaintiff "offer[s] no analysis" and "merely proffer the adverse event reports by themselves.").

Circuit.[38] No other Circuit Court of Appeal has held to the contrary.[39] And this question presents an issue of first impression for the Eighth Circuit.

The difference in the aforementioned approaches highlights the substantial ground for disagreement on this issue. Here, and in *Teva*, the Court held that it *cannot conclude that plaintiff did not meet* her burden. By contrast, the First and Second Circuits (and various district courts) held that it *must reach a conclusion that plaintiffs did (or did not) meet* their burden after scrutinizing plaintiffs' allegations, including the underlying evidence, to ensure that the alleged information meets the regulatory definition of newly acquired information to properly exercise its obligations under *Albrecht*. This Court's, and the *Teva* court's, failure to determine if plaintiffs' allegations actually meet the regulatory definition of newly acquired information by scrutinizing the alleged "new" evidence is contrary to the approach taken by other district courts and other Courts of Appeals. Thus, there is a substantial ground for disagreement on this issue based on these conflicting decisions.

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[38] The United States District Court for the Western District of Arkansas took a different approach in *Stube v. Pfizer Inc*., 446 F. Supp. 3d 424 (W.D. Ark. 2020). In *Stube*, plaintiff alleged that defendant failed to warn of certain risks prior to her exposure to defendant's drug. *Id.* at 437. Defendant moved to dismiss and the court considered whether plaintiff met its burden of alleging facts that the defendant could have unilaterally changed a label because of newly acquired information. In denying defendant's motion, the court did not simply accept that plaintiff alleged "new" information. *Id.* Rather, the court scrutinized the alleged new information to determine whether "newly acquired information existed that revealed 'risks of a different type or greater severity or frequency than previously included in submissions to FDA.'" *Id.* Specifically, the court considered 47,287 adverse event reports and "several medical studies, trials, and analyses *reporting heightened incidence rates . . . much higher than previously known*." *Id.* Based on this new information, the court concluded that plaintiff actually alleged "the existence of newly acquired information that showed risks . . . *that were of a different or greater severity or frequency* than what had been previously disclosed to the FDA." *Id.*

[39] *See also Knight v. Boehringer Ingelheim Pharm., Inc.*, 984 F.3d 329, 338 (4th Cir. 2021) (granting defendant's renewed motion for judgment as a matter of law holding that plaintiff's claims were preempted because the study plaintiff alleged as new information did not reveal risks of a different type or greater severity or frequency of bleeding risk associated with Pradaxa than previously included in submissions to the FDA).

Finally, there is a substantial ground for difference of opinion regarding the Court's conclusion that the issue of preemption "is a question of fact for a jury to resolve."[40] Other courts, including the United States Supreme Court and district courts in the Eighth Circuit, have disagreed and held that the preemption question "is a legal one for the judge, not a jury."[41] NPC is aware of no court, since the Supreme Court's decision in *Albrecht*, that has ruled that the issue of preemption is a question of fact for the jury to decide. Thus, there is a substantial ground for disagreement on this issue based on these conflicting decisions.

II. THE COURT SHOULD STAY THIS LITIGATION PENDING THE COURT OF APPEALS' RESOLUTION OF NPC'S PETITION FOR LEAVE TO APPEAL.

The Court has the inherent power to stay an action to control its docket, conserve judicial resources, and provide a just determination of the case.[42] Reflecting this discretion, section 1292(b) provides that an application for an appeal does not stay proceedings in the district court unless a stay is ordered.[43] In determining whether a stay is warranted, a district court considers "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues; and (3) whether discovery is complete and whether a trial date has been set."[44] All three factors weigh in favor of a stay of this case.

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[40] Filing No. 51 at 11.

[41] *See, e.g.*, *Ridings*, 444 F. Supp. 3d at 980 (quoting *Albrecht*, 139 S. Ct. at 1679) (holding *Albrecht* preemption hearing and finding claims preempted by the FDCA); *see also Duncan*, 2020 WL 6204563, at *6 (stating that preemption is for the judge, not the jury).

[42] *Lunde v. Helms,* 898 F.2d 1343, 1345 (8th Cir.1990) (*citing Landis v. North American Co.*, 299 U.S. 248, 254 (1936)); *see also Clinton v. Jones,* 520 U.S. 681, 706 (1997) (A federal district court "has broad discretion to stay proceedings as an incident to its power to control its own docket.").

[43] 28 U.S.C. § 1292(b).

[44] *See Schwendimann*, 2012 WL 5389674, at *5 (internal quotations and citation omitted)

A stay would not create any undue prejudice or disadvantage to the plaintiffs. Indeed, a stay would conserve the resources of all parties and the Court. The Order will create substantial additional expenditures of time and expense by all parties and the Court. If, however, the Eighth Circuit hears and overturns the Order on the issues raised by NPC's Motion to Certify then all of this effort and expense will be for naught.[45]

The other two factors also support a stay. A stay would simplify the issues in this case by affording the Eighth Circuit an opportunity to clarify fundamental issues upon which future proceedings in this case will be dependent. Moreover, this case was filed early this year and discovery has not started and no trial date has been set. These factors therefore favor a stay.[46]

In sum, a stay pending an appeal of the Order is justified because the requested stay would clearly conserve judicial resources and provide a just determination of the case.[47]

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[45] *See Moore v. Apple Cent., LLC*, No. 5:16-CV-05069, 2017 WL 11195761, at *2 (W.D. Ark. March 16, 2017) (recognizing that "the time and expense of the parties" from litigating under a debatable issue "will be more harmful to each of them than simply staying pending resolution of an appeal"); *Stearns v. NCR Corp.*, No. 98-2348 (JRT/FLN), 2000 WL 34423090, at *2 (D. Minn. Oct. 11, 2000) (granting stay, even with possible delay of health care benefits to plaintiffs, to avoid investment of "unnecessary time and resources which, by certifying its Order for appeal, the Court has sought to avoid").

[46] *See Schwendimann*, 2012 WL 5389674, at *6 (finding stay appropriate where it would "avoid[] potentially unnecessary litigation" and where discovery would "not be completed for another six months, and the case [would] not be trial ready for another year").

[47] District courts in the Eighth Circuit have not hesitated to stay proceedings pending resolution of a 1292(b) interlocutory appeal. *See*, *e.g.*, *Moore*, 2017 WL 11195761, at *2; *Grant v. Convergys Corp.*, No. 4:12-CV-496 (CEJ), 2013 WL 1342985, at *3 (E.D. Mo. April 3, 2013); *Delock*, 883 F. Supp. 2d at 792; *Schwendimann*, 2012 WL 5389674, at *6; *H&R Block Tax Servs., LLC v. Franklin*, No. 10-01165-CV-W-DW, 2011 WL 13233811, at *2 (W.D. Mo. Nov. 16, 2011); *Perry*, 2010 WL 546774, at *4; *Pro- Edge*, 2006 WL 8456918, at *3; *Stearns*, 2000 WL 34423090, at *2.

CONCLUSION

For the foregoing reasons, the Court should certify its September 8 Order for interlocutory appeal and stay proceedings in this action until the Eighth Circuit resolves NPC's petition for appeal and any resulting interlocutory appeal.

Dated: September 22, 2021

Respectfully submitted,

NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.

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CERTIFICATE OF COMPLIANCE WITH NECivR 7.1(d)(4)

I hereby certify that the Defendant Novartis Pharmaceuticals Corporation's Memorandum in Support of its Motion to Certify Order Under 28 U.S.C. § 1292(b) For Interlocutory Appeal And For Stay Of Proceedings (Filing No. 54) complies with the type-volume limitations of NECivR 7.1(d)(4) because it contains 5,313 words. This word count includes all text, including the caption, headings, footnotes, and quotations. I have relied on Microsoft Office Home and Business 2019-word processing software used to prepare the memorandum for the statement of word count.

/s/ Michael K. Huffer
Attorney for Defendant Novartis Pharmaceuticals Corporation